

Summary of Safety and Effectiveness

SEP 21 2011

NAME OF SPONSOR:	Ortho Development Corporation 12187 South Business Park Drive Draper, Utah 84020
510(k) CONTACT:	Tom Haueter Regulatory Affairs Manager Telephone: (801) 553-9991 Facsimile: (801) 553-9993 Email: thaueter@orthodevelopment.com
DATE PREPARED:	Date: June 13, 2011
PROPRIETARY NAME:	Ortho Development BioloX Delta Ceramic Femoral Heads
COMMON NAME:	Femoral head
CLASSIFICATION:	21 CFR 888.3353, Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis; Class II device
DEVICE PRODUCT CODE:	LZO
PREDICATE DEVICES:	Ortho Development Ceramic Femoral Head with Press-fit Stems <i>Ortho Development Corp.</i> (K053587) Ortho Development Ceramic Femoral Head <i>Ortho Development Corp.</i> (K060577) Smith & Nephew BioloX Delta Ceramic Femoral Heads <i>Smith & Nephew, Inc.</i> (K083762)

DEVICE DESCRIPTIONS:

The Ortho Development BioloX Delta Ceramic Femoral Heads mate with the existing Ortho Development Ovation and Encompass 12/14 taper femoral hip stems and articulate against Ortho Development polyethylene acetabular liners. The femoral heads are available in 28mm, 32mm, 36mm, and 40mm diameters in a variety of offsets.

INDICATIONS FOR USE:

The Ortho Development BioloX Delta Ceramic Femoral Head is intended for use in total hip arthroplasty procedures with the Ovation Hip Stem System (indicated for uncemented, biological fixation of the stem) and the Encompass Hip Stem System (indicated for both cemented and uncemented, biological fixation of the stem).

Total hip arthroplasty is indicated for the following conditions:

1. Notably impaired hip joints due to osteoarthritis, rheumatoid arthritis and/or post traumatic arthritis.
2. Previously failed hip surgery.
3. Fractures of the femoral neck or head.
4. Avascular necrosis of the femoral head.
5. Congenital dysplasia or other structural abnormalities where sufficient bone stock exists to properly seat the prosthesis.

BASIS OF SUBSTANTIAL EQUIVALENCE:

Ortho Development BioloX Delta Ceramic Femoral Heads are substantially equivalent to the previously cleared predicate devices based on similarities in intended use, design, materials, size range, manufacturing methods, packaging, sterilization method, and mechanical performance.

Mechanical testing data demonstrates that the Ortho Development BioloX Delta Ceramic Femoral Heads are equivalent to currently marketed devices and able to withstand expected in vivo loading. This is demonstrated in burst fracture, taper disassemble (pull off) and wear tests as described in the Summary of Design Control Activities.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -W066-G609
Silver Spring, MD 20993-0002

Ortho Development Corporation
% Mr. Tom Haueter
Regulatory Affairs Manager
12187 South Business Park Drive
Draper, Utah 84020

SEP 21 2011

Re: K111936

Trade/Device Name: Ortho Development Biolox Delta Ceramic Femoral Head
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or
nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO
Dated: August 19, 2011
Received: August 22, 2011

Dear Mr. Haueter :

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Form
Ortho Development
Bilox Delta Ceramic Femoral Head 510(k)

510(k) Number (if known): K111936

Device Name: Ortho Development Biolox Delta Ceramic Femoral Head

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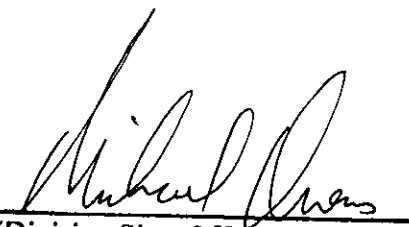
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4. Avascular necrosis of the femoral head.
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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)


(Division Sign-Off) for MxM
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111936